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10/748,114	12/29/2003	Carlos F. Vonderwalde	R0495-01201	1742

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EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/748,114

Applicant(s)

VONDERWALDE ET AL.

Examiner

Pavitra Kotini

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-81 is/are pending in the application.
- 4a) Of the above claim(s) 63-65 and 77-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-62, 66-73, 75 and 76 is/are rejected.
- 7) ☒ Claim(s) 74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/27/06, 4/22/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election **without** traverse of Group I, claims 47-62 and 66-76, in the reply filed on January 16, 2007 is acknowledged. In the previous office action, the examiner mistakenly classified claims 63-65 (method claims) as part of Group I when they should in fact belong to Group II. Therefore, claims 63-65 and 77-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-46 are cancelled.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 54** rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: wall sections are part of said *stent* tubular body. The claim needs to be made clear that the wall sections are actually a part of the stent.

**Claim 58** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically it is unclear whether "a first end of said stent cover..." is referring to the same limitation recited in claim 51 as "a first cover end" or if there is a new limitation is being introduced.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 47-50 and 54-62** are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (US-6042605). Martin discloses a stent assembly, comprising:

Regarding **claim 47**, a stent (6) including a substantially tubular body with openings in walls of said tubular body (fig. 1-10), a first stent end (fig. 1A, left side of stent assembly) and a second stent end (fig. 1B, right side of stent assembly); and a stent cover (8), disposed in part on the outside of said tubular body and in part under a portion of said wall (fig. 8, cover 8 is disposed over and under the walls of stent 6).

Regarding **claim 48**, said stent cover is substantially a sheet of material rolled into said substantially tubular shape (fig. 1-10).

Regarding **claim 49**, wherein said stent cover is substantially a tube (figs. 1-10).

Regarding **claim 50**, wherein part of said stent cover passes through said openings in said walls (fig. 1-10).

Regarding **claim 54**, The stent assembly of claim 47, wherein said tubular body comprises plurality of substantially ring-shaped wall sections (figs. 1-3A, 4, 6-10; stent 6 contains serpentine bands or undulating portions) with at least one connecting member (20) extending between any two adjacent wall sections including a first terminal wall

Art Unit: 3731

section at said first end (fig. 1A, left side of stent assembly), a second terminal wall section at said second end (fig. 1B, right side of stent assembly) and at least one inner wall section (any section in between first end and second end) between said first terminal wall section and said second terminal wall section and wherein said part of said stent cover disposed under said portion of said wall is disposed under at least part of a said wall section (cover 8 disposed under stent 6 is inherently disposed under wall section as well).

Regarding **claim 55**, said stent cover is disposed over an inner wall section adjacent to said first terminal wall section (fig. 1B).

Regarding **claim 56**, wherein said stent cover (8) is disposed over at least one said connecting member (20) extending between said first terminal wall section and an inner wall section adjacent thereto (fig. 3B).

Regarding **claim 57**, wherein said terminal wall section (left end of stent 6) has an undulated structure (serpentine bands) and wherein said portion of said stent cover (8) disposed under a part of said first terminal wall section is disposed under at least one undulation (14) of said first wall section (figs. 6-10).

Regarding **claim 58**, wherein a first end of said stent cover is disposed under undulations of said first terminal wall section (figs. 6-10).

Regarding **claim 59**, wherein said first terminal wall section (left end portion of stent 6) has a first end and a second end (if stent 6 is flattened out, the top is a first end and the bottom is a second end) and wherein maxima of said undulated structure are

substantially located at said first end and at said second end of said first terminal wall section (figs. 1-3A, 4, 6-10).

Regarding **claim 60**, wherein said first end of said first terminal wall section is substantially located at said first stent end (left end serpentine band with undulations 14 or wall section is at the left end of stent 6), and wherein a said connecting member (20) connecting said first terminal wall section and an inner wall section immediately adjacent thereto is attached to a maximum of an undulation located at said first end of said first terminal wall section (fig. 2).

Regarding **claim 61**, wherein a portion of said tubular body is configured to secure said stent cover to said stent (figs. 1-3A, 4, 6-10).

Regarding **claim 62**, wherein said tubular body is provided with at least one conver connector (10) including a penetrating element to penetrate said stent cover thereby securing said stent cover to said stent (FEP coating is penetrates surface of stent cover 8 and stent 6; col.7, lines 48-51).

**Claims 66-73, 75, and 76** rejected under 35 U.S.C. 102(b) as being anticipated by Bynon et al. (US-5667523). Bynon discloses a stent assembly comprising:

Regarding **claim 66**, an expandable tubular stent body (72) including a first stent end (12) and a second stent end (14); a substantially tubular stent cover (62) including a first cover end (64) and a second cover end (66) in contact with a surface of said stent body; and bendable cover connectors (62) disposed at the periphery of said first stent end and folded over said first cover end (col.12, lines 61-66).

Regarding **claim 67**, cover connectors (62) disposed at the periphery of said second stent end and folded over said second cover end (col.12, lines 61-66).

Regarding **claim 68**, wherein said stent cover is in contact with an inner surface of said stent body (due to the undulations and openings within the stent body, the stent cover 62 is considered to be in contact with the inner surface).

Regarding **claim 69**, wherein said stent cover is in contact with an outer surface of said stent body (fig. 13).

Regarding **claim 70**, wherein said cover connectors are integrally formed with said stent body (col.12, lines 61-66).

Regarding **claim 71**, a first ring-shaped wall section (76) defining said first stent end (12), wherein part of an end thereof is a said cover connector (62) folded over said first cover end (64); and a second ring-shaped wall section (78) defining said second stent end (14), wherein part of an end thereof is a said cover connector (62) folded over said second cover end (66) (fig. 11).

Regarding **claim 72**, wherein said first ring-shaped wall section is substantially a bent wire loop (68, fig. 11).

Regarding **claim 73**, wherein said wire loop is bent in an undulate fashion so that said first ring-shaped wall section is substantially cylindrical (68 fig. 11).

Regarding **claim 75**, wherein said stent cover is substantially a rolled up sheet (62) so that a first edge and a second edge of said sheet substantially abut (fig. 11).

Regarding **claim 76**, wherein said stent cover (62) is substantially a rolled up sheet (fig. 11) so that a first edge and a second edge of said sheet overlap (old and well known in the art).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 51-53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US- 6042605).

Regarding claims 51- 53, Martin discloses said cover is substantially tubular in shape (figs. 1-10) comprising a first cover end (one end of ribbon cover 8), a second cover end (other end of ribbon cover 8) and an intermediate section there between (ribbon cover 8 in between the two ends)

Martin does not disclose precisely that said first cover end and second cover end are disposed under a portion of said wall.

However, Martin clearly teaches various conformations of the ribbon cover 8 with stent 6 (col.7, lines 30-45). Therefore, it would have been obvious by the teachings of martin to one of ordinary skill in the art that ribbon cover 8 could be manipulated to be placed under or over stent 6 at various places along the length of the stent. Such a modification would render the prior art and the claimed invention analogous and provide



Art Unit: 3731

the advantages of either ensuring the end portions of the cover are secured under the stent or the intermediate portions are secured under the stent.

***Allowable Subject Matter***

**Claim 74** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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2/19/07